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(54) **DERMAL PHASE METER WITH IMPROVED REPLACEABLE PROBE TIPS**

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This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

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(51) **Int. Cl.**

G01R 31/02 (2006.01)

G01R 31/28 (2006.01)

(52) **U.S. Cl.** **324/761; 324/754; 324/158.1**

(58) **Field of Classification Search** **324/761**
See application file for complete search history.

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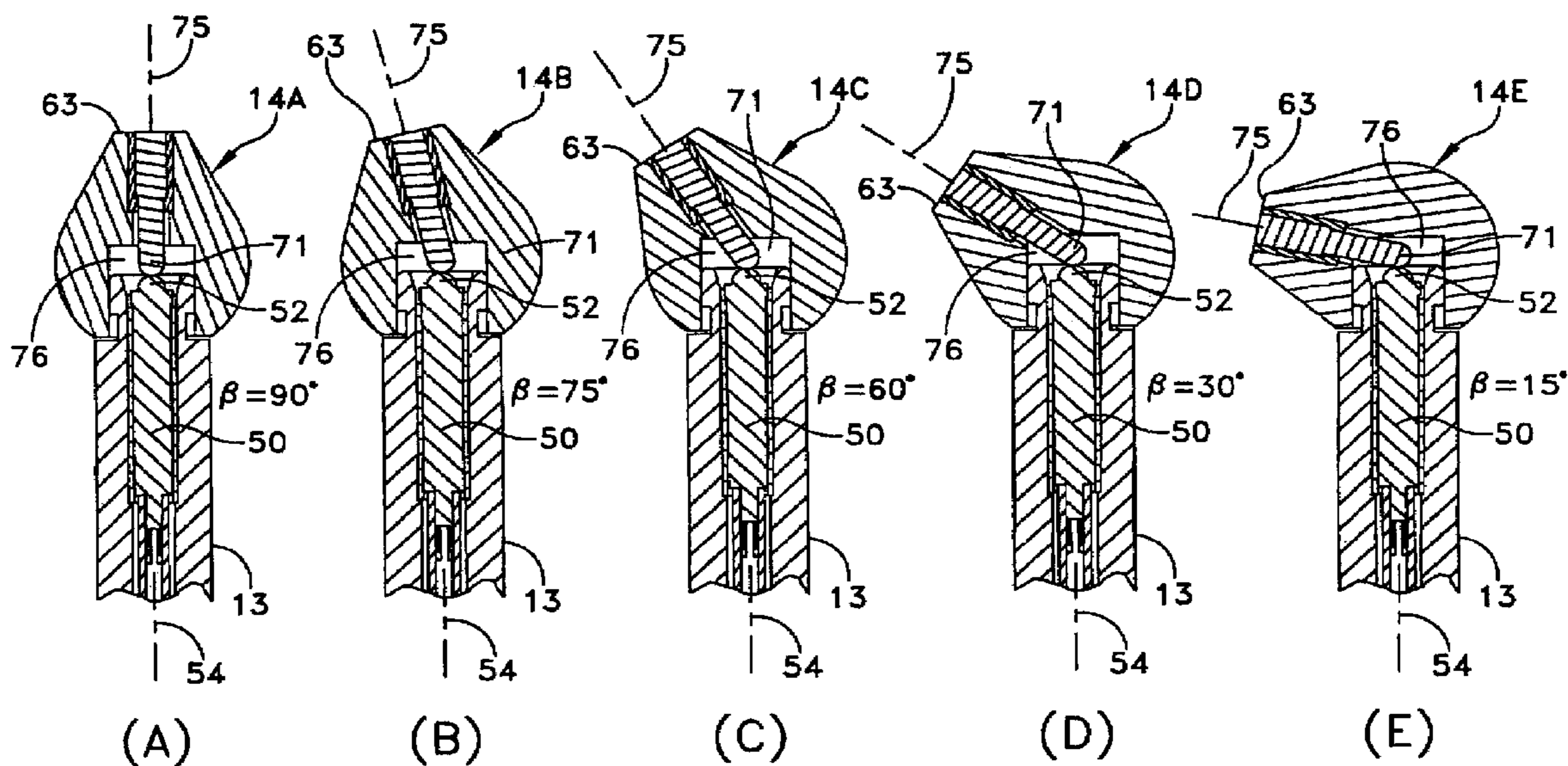
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(57) **ABSTRACT**

A probe for a dermal phase meter includes a handle with a removable extension that terminates with a displaceable center conductor. A replaceable tip attaches to the distal end of the extension and includes a center conductor that engages the center conductor in the extension and an outer conductor that establishes electrical connection through the extension. Substituting different replacement tips provides a probe with an articulation capability.

4 Claims, 9 Drawing Sheets



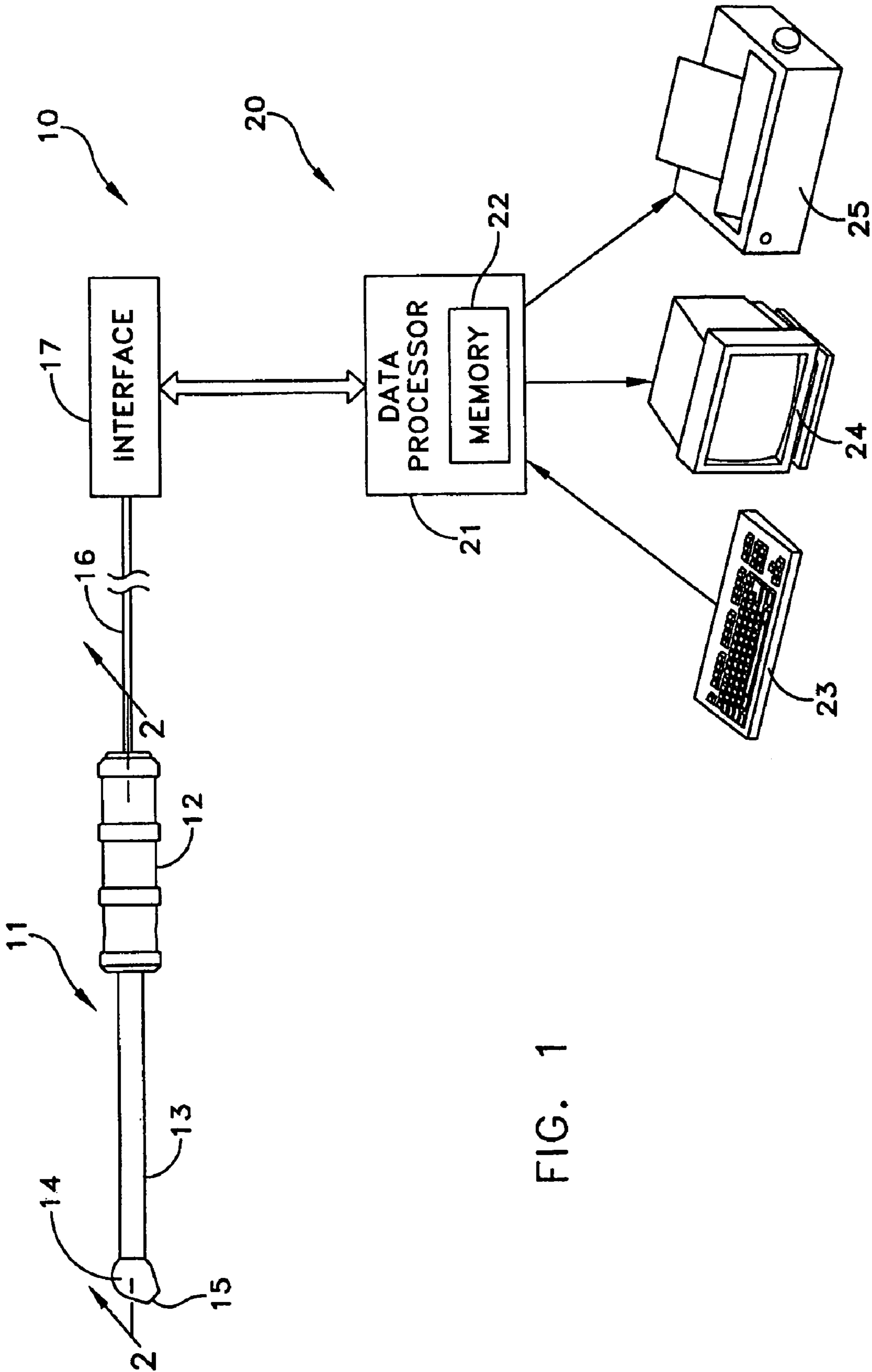


FIG. 1

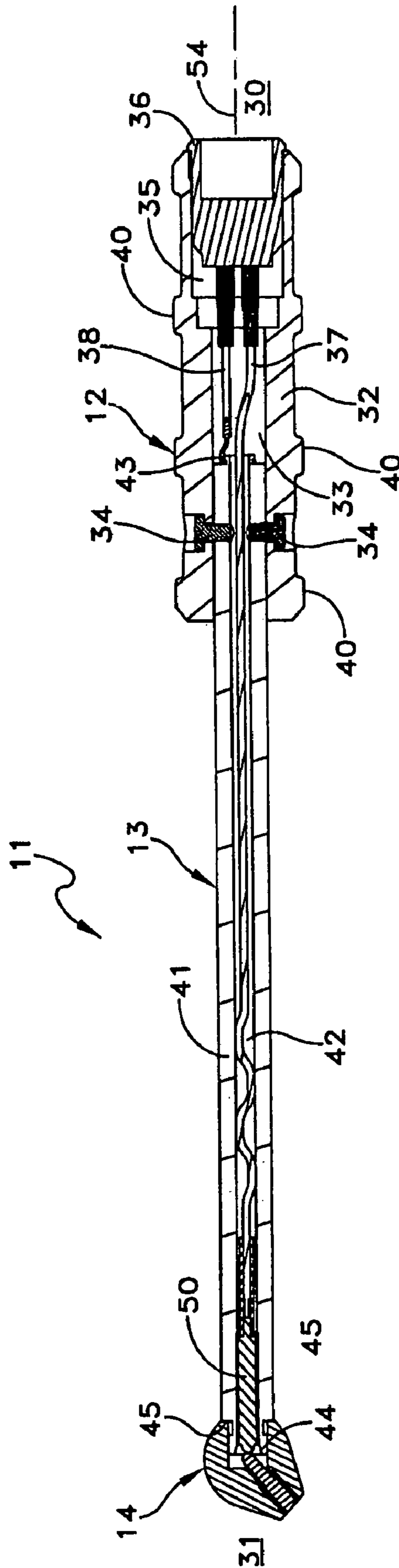


FIG. 2

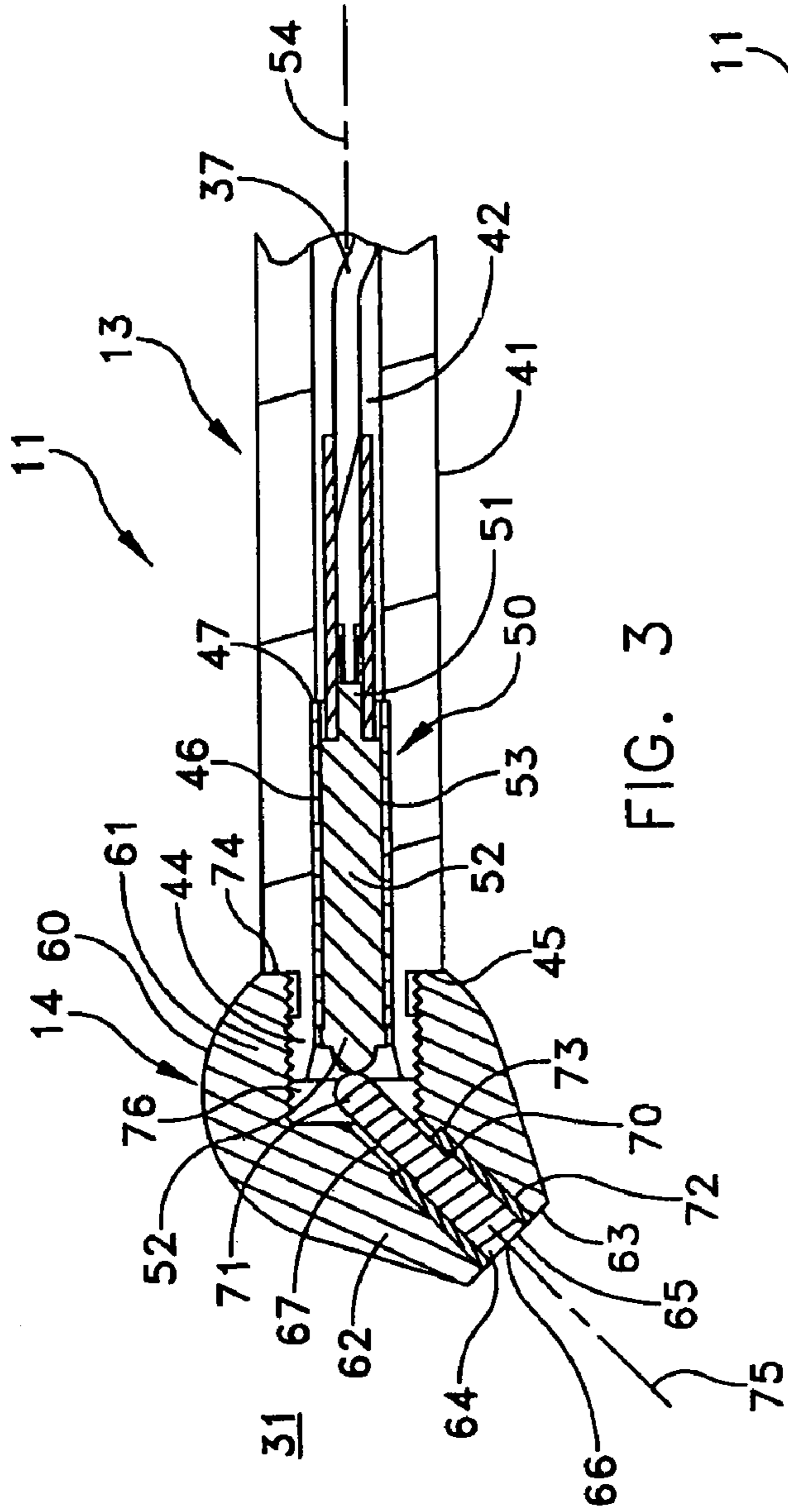


FIG. 3

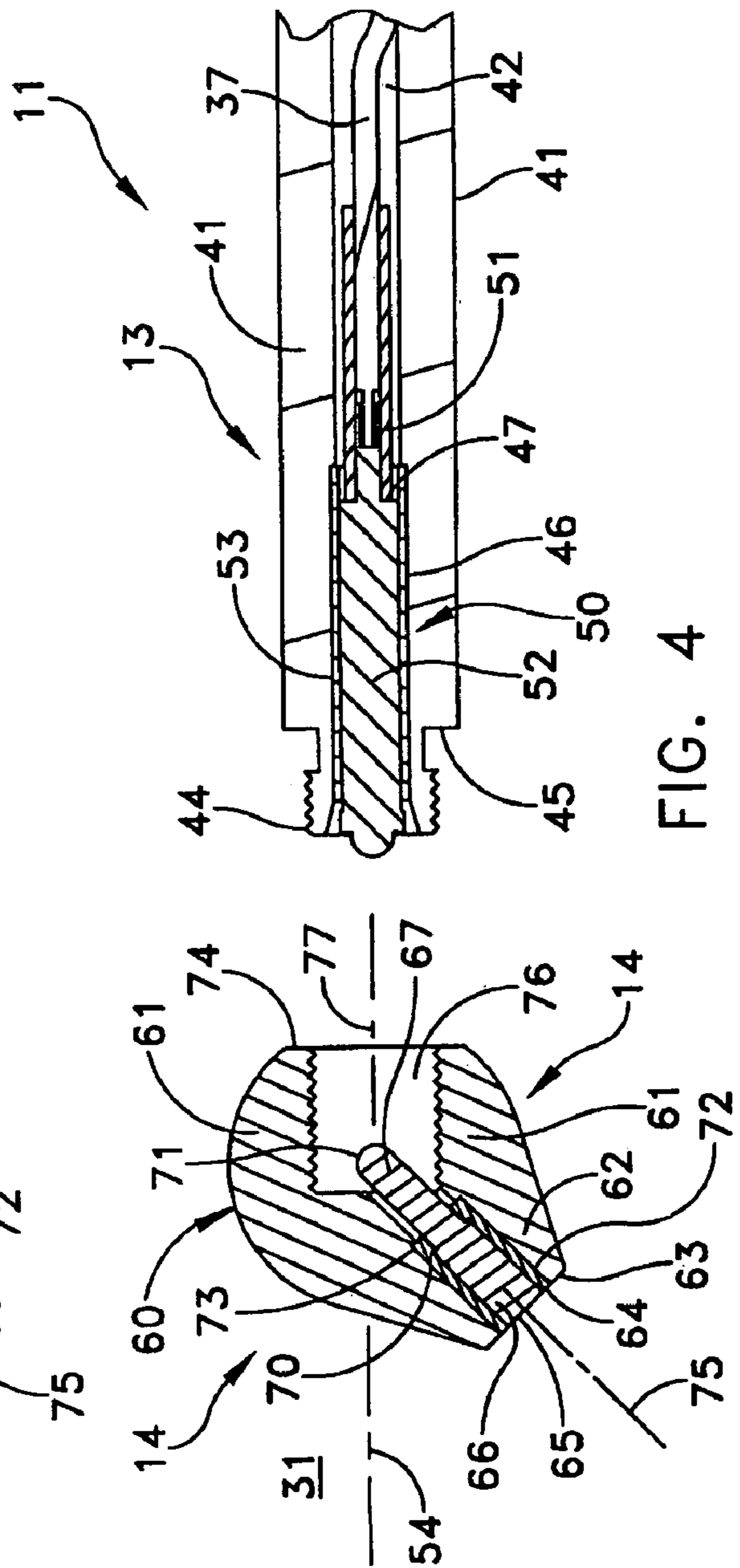


FIG. 4

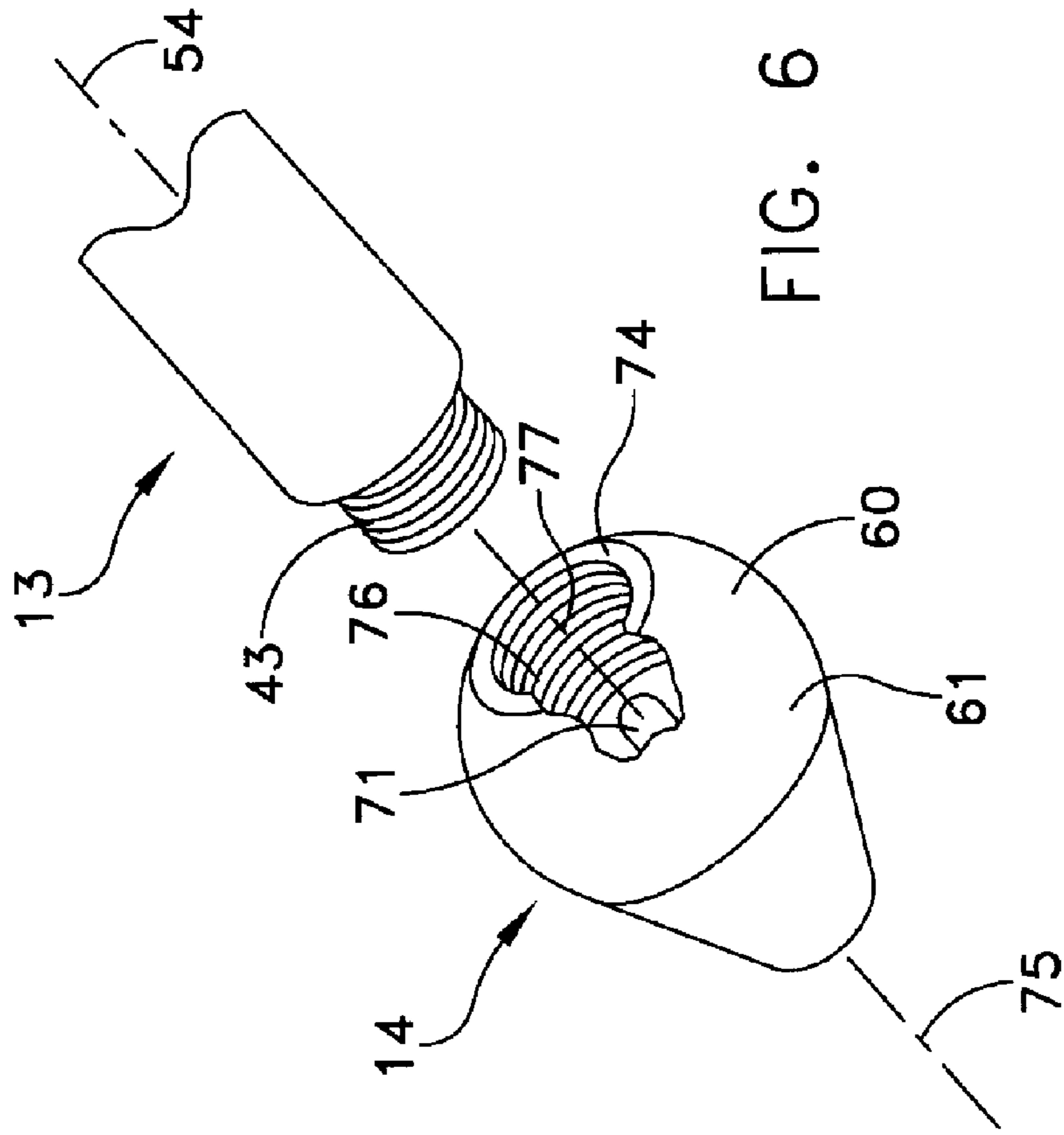


FIG. 6

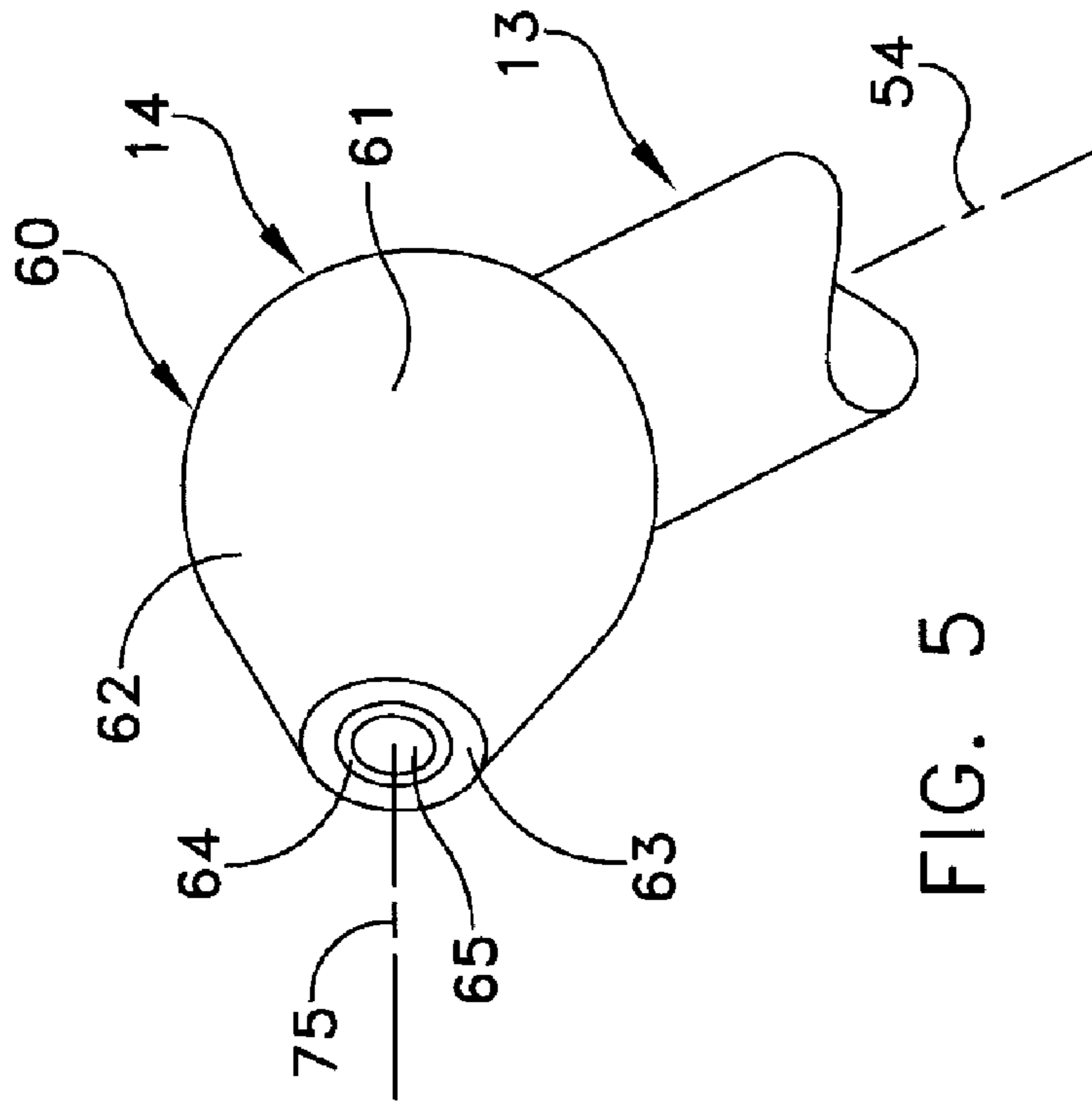


FIG. 5

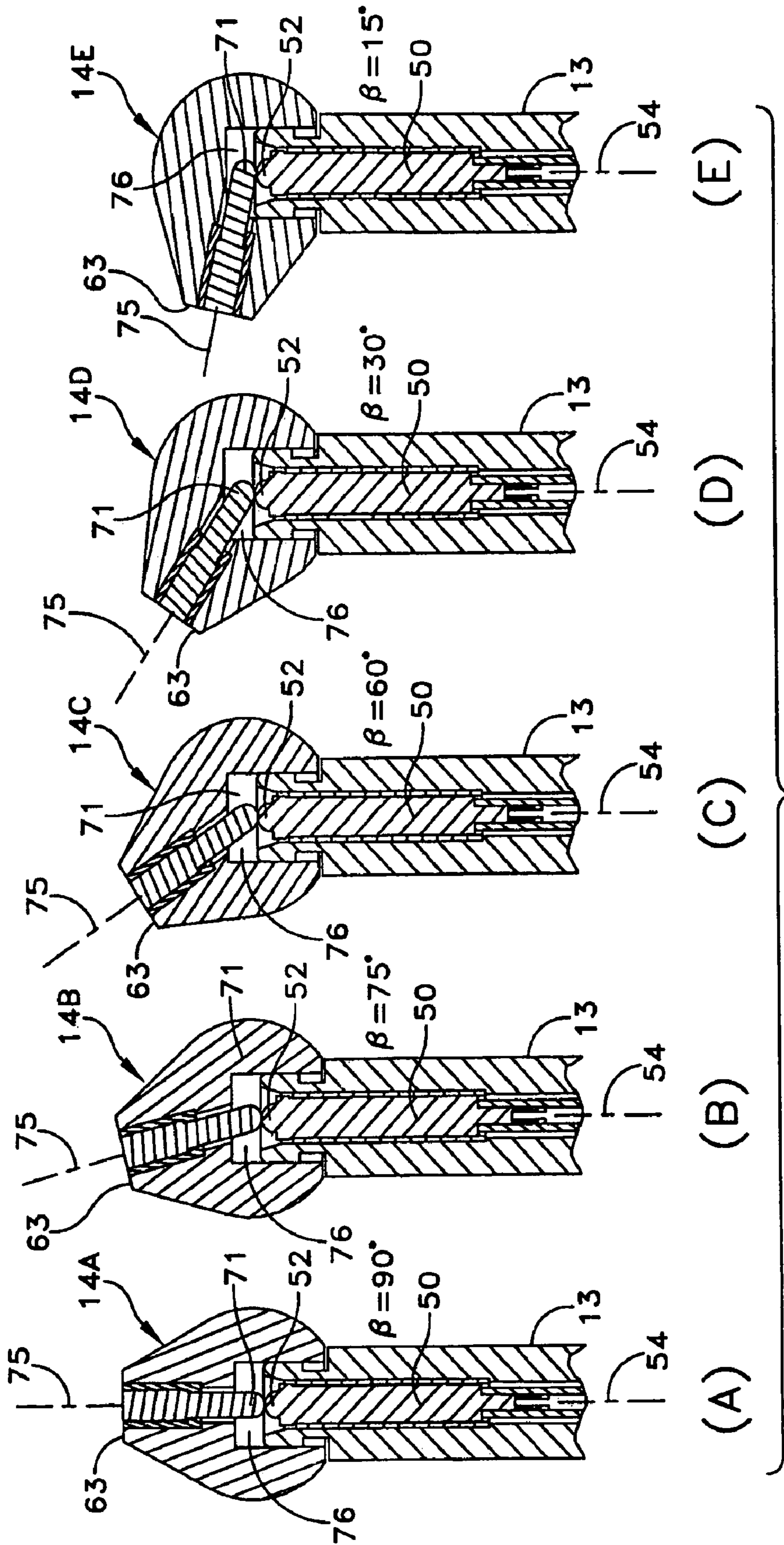
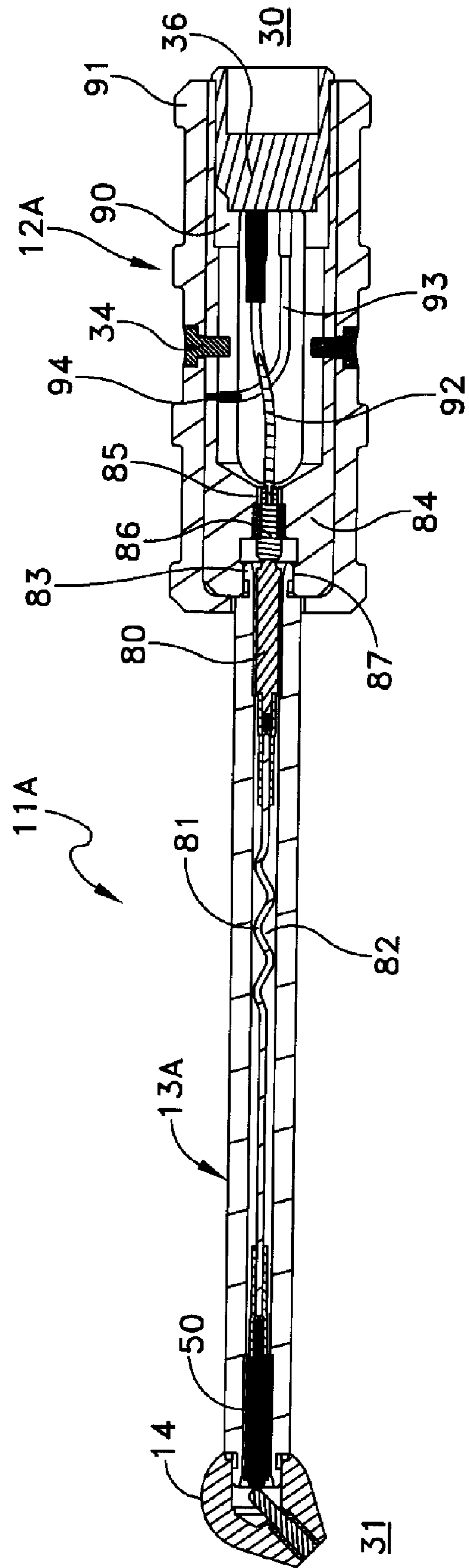


FIG. 7



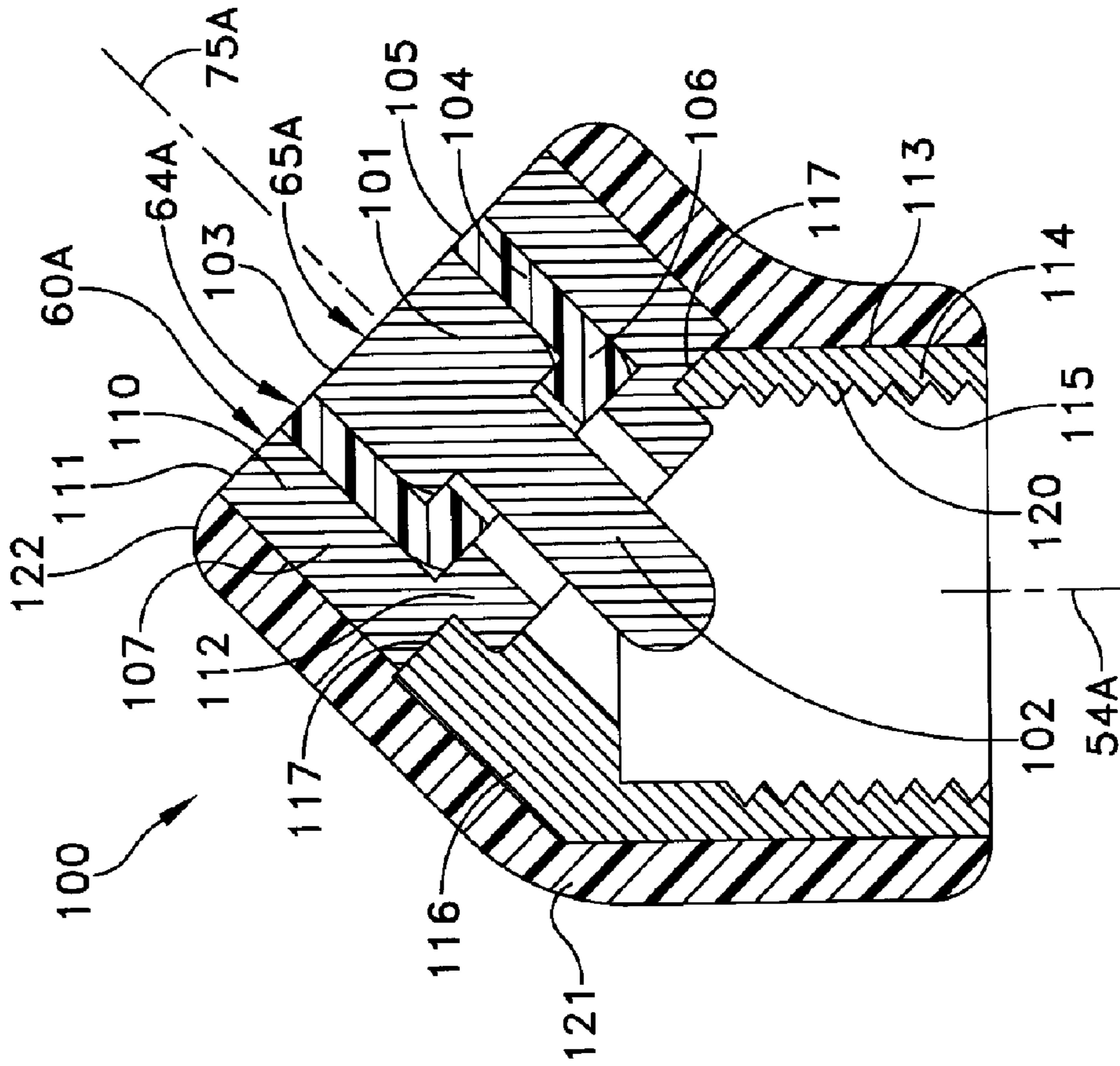


FIG. 9B

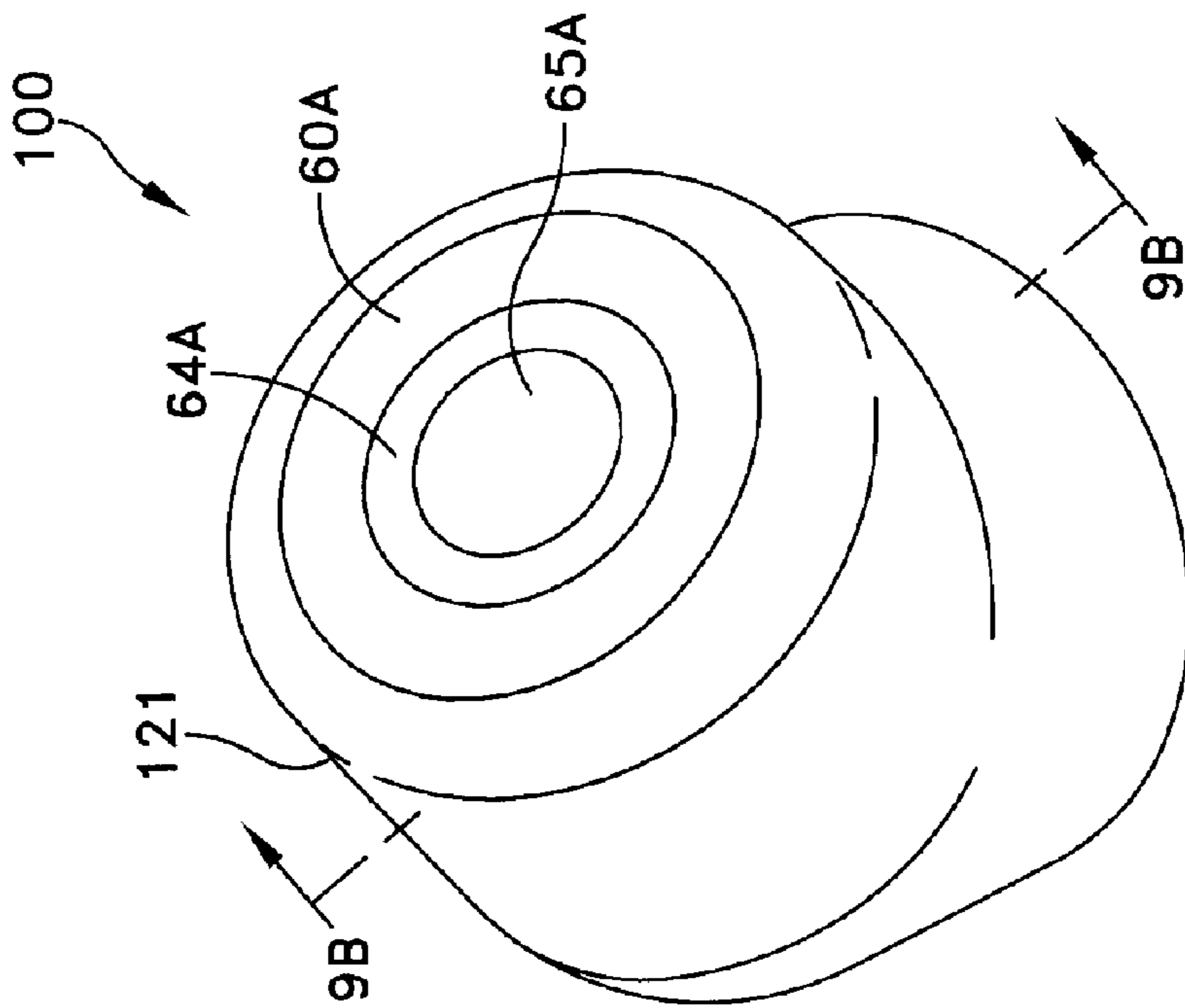


FIG. 9A

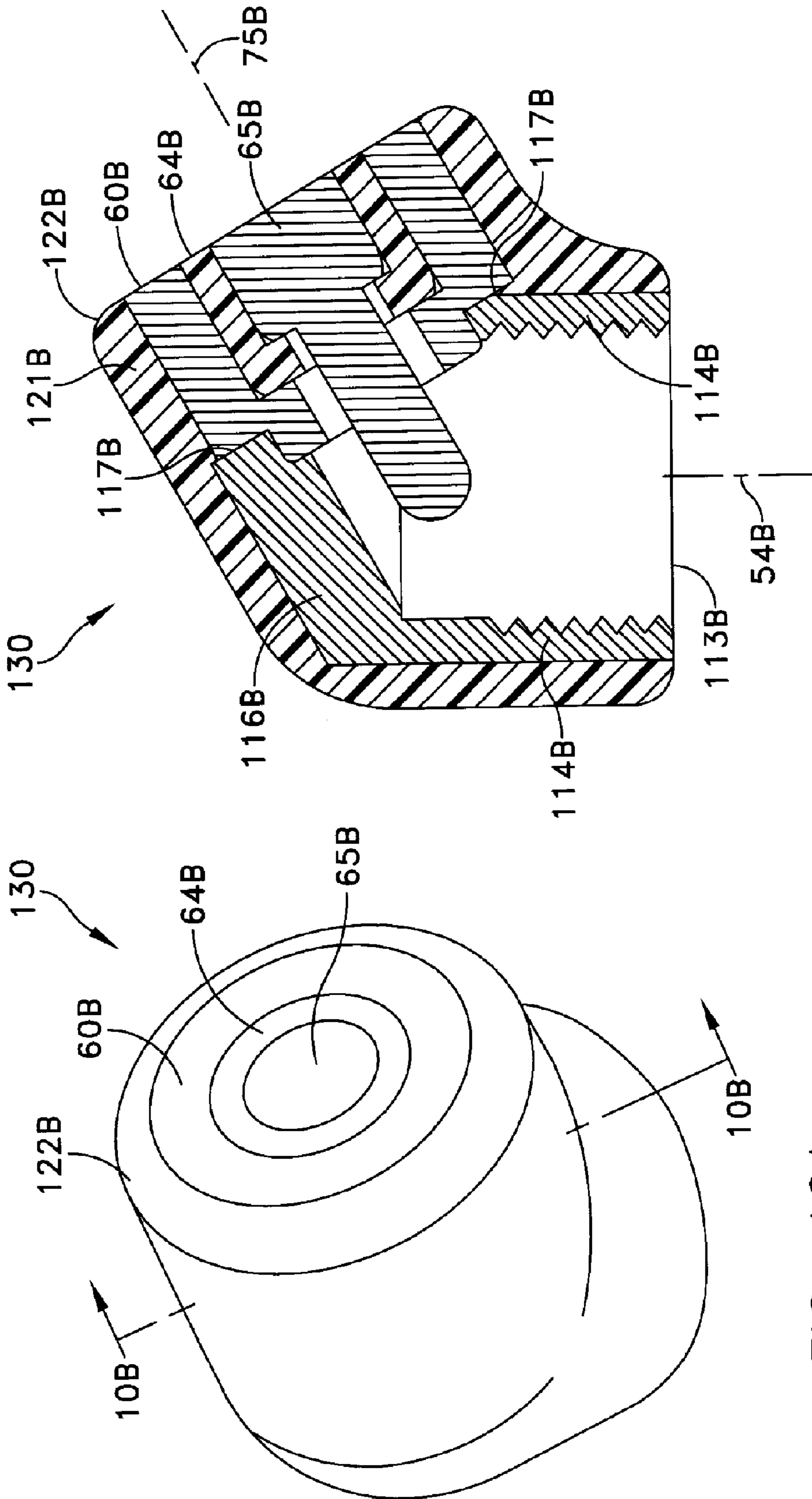


FIG. 10A

FIG. 10B

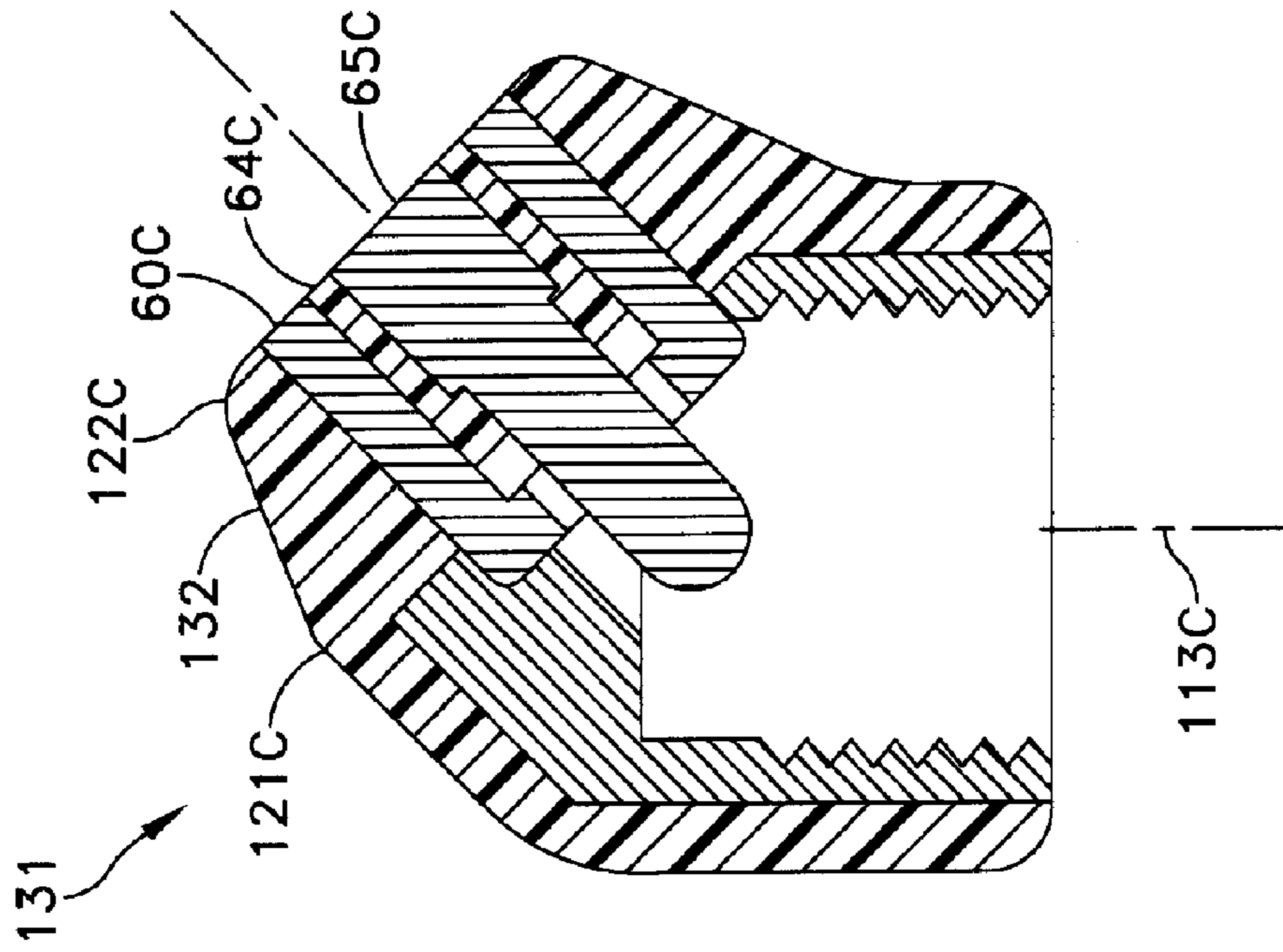


FIG. 11B

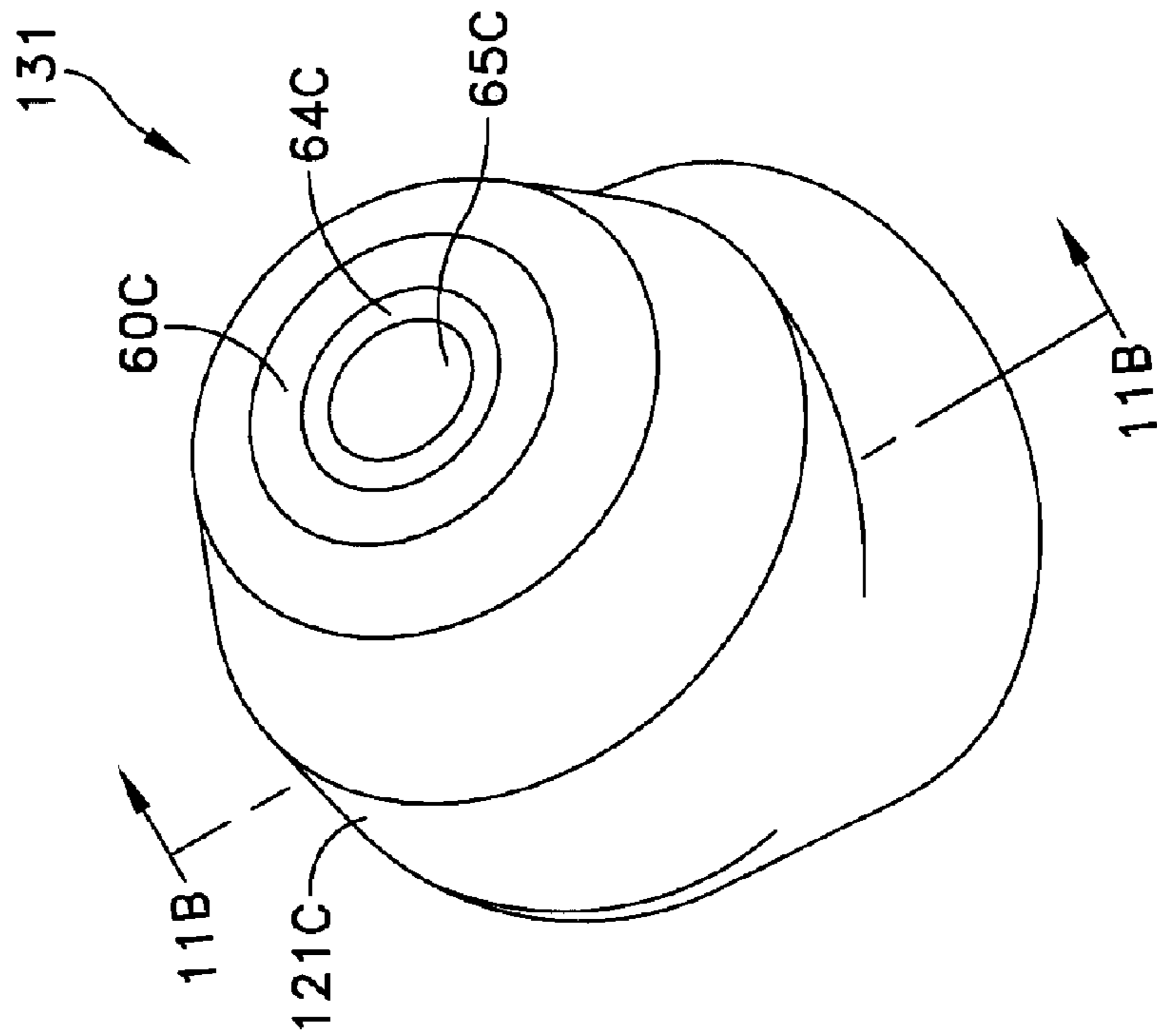


FIG. 11A

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**DERMAL PHASE METER WITH IMPROVED
REPLACEABLE PROBE TIPS****CROSS REFERENCE TO RELATED
APPLICATION**

This application is a continuation-in-part of application for U.S. patent Ser. No. 10/908,327 filed May 6, 2005; now U.S. Pat. No. 7,161,364, for a Dermal Phase Meter with Replaceable Probe Tips.

FIELD OF THE INVENTION

This invention generally relates to dermal phase meters and more specifically to a probe that can broaden the applications for such dermal phase meters.

DESCRIPTION OF RELATED ART

Over the years there has been a growing interest in measuring the relative hydration of a substrate, such as the skin, for determining certain biophysical characteristics. U.S. Pat. Nos. 5,961,471 and 6,370,426 disclose different probes for obtaining such measurements. U.S. Pat. No. 5,961,471 to Nickson particularly discloses a probe for biophysical skin measurements that includes a disposable sensor and a handle for receiving a cable from a measurement device. A socket on the handle electrically interconnects with the cable. This disposable sensor removably engages the socket. When engaged, the sensor electrically interconnects with the cable for providing measurement signals concerning the biophysical skin measurement.

It now appears that measurements from such dermal phase meters may be used in models to indicate other medical conditions by applying a sensor to internal tissue, such as in the oral, anal, otic and nasal passages. Certain investigations are determining the efficacy of modeling the evaluation of oral mucositis by making measurements at multiple regions in the oral cavity for erythema and ulcerations. Other investigations are directed to determining the efficacy of such instruments in evaluating trauma, particularly hemorrhagic shock.

Probes, such as shown in the above-identified references, tend to be cumbersome and have a sensing surface that lies in a measurement plane that is orthogonal to a probe axis. To extend dermal phase meters to these new modalities, it has become important that the probes must be smaller. However, even smaller probes may be difficult to position within a cavity when the measurement plane is orthogonal to the probe axis. Probes characterized by a fully articulated measurement plane are complex and not particularly adapted to miniaturization. Moreover, many prior art probes terminate in solid, hard structures. Such structures can irritate sensitive tissue in these cavities.

What is needed is a probe that provides an articulation function, that is simple to use and that is economical to produce and that minimizes the potential for irritating sensitive tissue during measurements.

SUMMARY

Therefore it is an object of this invention to provide a probe that minimizes tissue irritation.

Another object of this invention is to provide a probe that is adapted for altering the aspect of the measurement plane to the probe axis that minimizes the potential for the irritation of sensitive tissue.

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In accordance with one aspect of this invention a dermal phase meter system includes a data processing system and a probe for providing input to the data processing system. The probe comprises a set of probe tips, a probe tip support and an electromechanical connection. Each probe tip includes inner and outer electrodes spaced by an insulating medium lying in a measurement plane for obtaining a measurement. The probe tip support lies along a probe axis with means at a proximal end thereof for connection to the data processing system. The electromechanical connection has components on the distal end of the probe tip support and on each probe tip thereby to enable the electrical and mechanical attachment and detachment of a probe tip to the distal end of the probe tip support whereby each of the probe tips are characterized by establishing a different angular aspect between the probe axis and the measurement plane. At least one probe tip includes a patient compatible, compressible elastomeric layer about the outer electrode

In accordance with another aspect of this invention a probe for a dermal phase meter comprises a handle, a tubular extension and a replaceable probe tip. The handle has an externally insulated conductive body and a proximal electrical connector supported thereby. The tubular extension has a central passage along a probe axis attached to a distal end of the body. The extension has a threaded connection and an axially displaceable spring biased conductor assembly in said passage. The replaceable probe tip has an outer conductive body and first and second passages lying on first and second intersecting axes, an insulator in said first passage and a conductor supported by said insulator extending into said second passage with an internally threaded portion extending along the second axis for attachment to and detachment from said threaded connection on said extension, said outer conductive body having a patient compatible, compressible elastomeric layer about said outer electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

FIG. 1 schematically depicts a dermal phase meter with a probe having a given aspect between a probe axis and a measurement plane;

FIG. 2 is a longitudinal cross section of the probe shown in FIG. 1;

FIG. 3 is an enlarged detail of the distal end of the probe shown in FIG. 2;

FIG. 4 is an enlarged view corresponding to FIG. 3 with a probe tip separated from a probe handle;

FIG. 5 is a perspective view of a probe tip taken from the distal end of the probe in FIG. 1;

FIG. 6 is a perspective view of a probe tip taken from the proximal end;

FIG. 7 depicts probe tips at (A) through (E) with different aspects between the measurement plane and probe axis;

FIG. 8 depicts a longitudinal cross section of another embodiment of a probe;

FIG. 9A is a perspective view of one embodiment of a probe tip with a patient compatible, compressible elastomeric outer layer having a first aspect; and FIG. 9B is a cross section taken along lines 9B-9B in FIG. 9A;

FIG. 10A is a perspective view of one embodiment of a probe tip with a patient compatible, compressible elastomeric outer layer like the probe tip in FIG. 9A, but with another

angular aspect; and FIG. 10B is a cross section taken along lines 10B-10B in FIG. 10A; and

FIG. 11A is a perspective view of one embodiment of a probe tip with a patient compatible, compressible elastomeric outer layer that has a smaller diameter than the probe tip in FIG. 9A; and FIG. 11B is a cross section taken along lines 11B-11B in FIG. 11A.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

FIG. 1 depicts one embodiment of a dermal phase meter 10 that includes a probe 11. The probe 11 includes a probe tip support in the form of a handle 12 at a proximal end and an extension 13 intermediate the handle 12 and a distal probe tip 14. The distal tip 14 has measuring surface 15 that can have a variety of forms. Essentially the measuring surface 15 lies in a measurement plane defined by two electrodes spaced by an insulating medium.

Other conductors 16 couple the electrodes in the distal tip 14 to an interface 17 that includes various electronics for sampling data to read the signal developed across the electrodes at some sampling frequency. A data processing system 20 controls the operation of the probe 11 through the interface 17. The data processing system 20 includes a data processor 21 with a memory 22, an input device shown in the form of a keyboard 23, and one or more output devices, shown as a video display 24 and a hard copy printing device 25. As will be apparent the specific implementation of the data processing system 20 can take many forms that are well within the purview of persons of ordinary skill in the art.

Referring now to FIG. 2, the probe 11 extends from a proximal end 30 at the handle 12 to a distal end 31 at the probe tip 14. The handle 12 has a generally cylindrical body 32 with a receptacle 33 to receive the extension 13. In this specific embodiment, a fastener attaches the cylindrical body 32 to the extension 13. As an example, in FIG. 2 diametrically opposed machine screws 34 extend radially through the cylindrical body 32 to engage the extension 13.

The proximal end of the handle 12 also has a proximally facing receptacle 35 that receives a proximal electrical connector 36. The connector 36 is adapted to receive a cable, such as the cable 16 shown in FIG. 1. The connector 36 also has two conductors 37 and 38. The conductor 37 is insulated and extends from the connector 36 through the extension 13 to the tip 14 as described below. The conductor 38 attaches to the extension 13 by soldering or other means.

The cylindrical body 32 is formed from an engineering polymer, such as Delrin®, with axially spaced, circumferential beads or bands 40. The beads or bands 40 form a gripping surface for the probe 11. The cylindrical body 32 thereby constitutes an insulated handle.

In this embodiment, the extension 13 is formed as a tube 41 with a central passage 42. Although not shown, the exterior surface of the tube 41 has an insulating coating so it acts as an externally insulated conductive extension. This allows the tube 41 to act as a conductor for the signals received from the tip 14 and be handled without electrical contact by personnel. A proximal radial surface 43 provides a connection point for the conductor 38.

Referring now to FIGS. 2 through 4, at the distal end 31, the tube 41 terminates in an externally threaded head portion 44 and radial shoulder 45. As shown more clearly in FIGS. 3 and 4, an enlarged, elongated chamber 46 in the tube 41 extends to an internal radial shoulder 47. This chamber 46 receives an axially displaceable spring biased conductor assembly 50, also shown in FIG. 2. Referring again to FIGS. 3 and 4, such

assemblies are commercially available and comprise a proximal end connection 51 for the conductor 37, a center conductor 52 and an insulating housing 53. The assembly 50 includes an internal spring, not shown, that biases the center conductor 52 distally, along a probe axis 54. This structure provides a continuous conductive path between the center conductor 52 and the end connection 51 even as the center conductor 52 moves axially within the insulating housing 53. A P3325 Series Probe manufactured by Everett Charles Technologies is an example of such an assembly 50.

Still referring to FIGS. 3 and 4, a tip 14 constructed in accordance with this invention attaches to the extension 13 in FIG. 3 and detaches from the extension 13 in FIG. 4. As it will become apparent, each tip 14 constructed in accordance with this invention has certain, common characteristics and features. Referring to FIGS. 3 through 5, each tip 14 is formed from a solid bulbous conductive material, such as brass, to form an outer conductor 60 with a main enlarged bulbous body portion 61 and a conical portion 62 that tapers to a measuring surface 63. The tip 14 carries an insulator 64 and a central conductor 65 in a first passage extending along a measurement axis 75 orthogonal to the measuring surface 63 described later. The surface 63 formed by the ends of the outer conductor conical portion 62, insulator 64 and center conductor 65 defines the measurement plane thereby to provide a sensing surface by which a measurement is obtained. As with the tube 41, the surface of the outer conductor 60 will be coated with an insulating material.

The center conductor 65 has an enlarged shank portion 66 and a narrower portion 67 delimited by a shoulder 70. The end of the narrower shank 67 terminates in a semispherical conductor portion 71. The insulator 64, that is positioned in the conical section 62, overlies the larger shank portion 66 and has a cylindrical body 72 with a collar 73 that engages the shoulder 70. The reduced shank portion 67 including the semispherical tip 71 is isolated from the outer conductor 60. It will also be apparent that the center conductor 67 extends to intersect the probe axis 54.

The outer conductor 60 also includes a planar surface 74 that lies in a plane that is normal to another axis that, in FIGS. 3 and 4, is coincident with the probe axis 54. This first axis and probe axis 54 are angularly offset from the measurement axis 75 normal to the planar surface 63 at an angle β . More specifically, an internally threaded hole or passage 76 extends in the direction along an axis 77, as the first axis, that is perpendicular to the planar surface 74 and coincident with the probe axis 54. The angle β between the measurement axis 75 and the axis 77 defines the angular aspect of the measurement plane for the given probe tip 14. In this specific embodiment $\beta=45^\circ$.

A complementary electromechanical connection provides a means for mounting a detached probe 14, as shown in FIG. 4 onto the distal end of the extension 13 as shown in FIG. 3. Specifically, it is merely necessary to screw the tip 14 onto the threaded head portion 44 as shown in FIG. 3 whereby the axis 77 and probe axis 84 are coincident. As rotation of the probe tip 14 relative to the extension 13 continues, the probe tip 14 advances proximally until the semispherical conductor portion 71 engages and makes electrical contact with the distal end of the center conductor 52 of the assembly 50. The structures will be dimensioned so that this contact occurs prior to engagement of a radial shoulder that defines the planar surface 74 and the shoulder 45. Further advancement and tightening of the probe tip 14 advances the probe tip 14 proximally and forces a displacement of the center conductor 52 against the bias of the internal spring of the assembly 50. A comparison of FIGS. 3 and 4 depicts this displacement. As a result the center conductor 52 and the center conductor 65 maintain

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good electrical contact. The outer conductor **60** has good electrical contact with the tube **40** by virtue of the threaded engagement.

To achieve the articulation function, a measurement system as shown in FIG. **1** can be constructed with a set of a plurality of probe tips **14** each of which provides a different angular aspect between the probe axis and the measurement plane. While FIGS. **2** through **6** depict a probe with an angular aspect of 45° , FIG. **7** depicts probes (A) through (E) with the measurement plane defined by the end **63** surface at different angular aspects. That is, each differs by the orientation of the probe axis **54** and coincident first axis (not shown in FIG. **7**) and the measurement axis **75**. For example, FIG. **7A** depicts a probe tip **14A** that provides a 90° aspect of the measurement plane defined by the surface **63** and the probe axis **54**. In this particular case the hole **76** extends along the axis **75**. Contact with the center conductor **52** is shown. At (B) in FIG. **7** a tip **14B** in which the axis **75** through the hole **76** is offset to provide a 75° aspect. The probes at (C) through (E) depict distal tips **14C**, **14D** and **14E**, which provide aspects of 60° , 30° and 15° respectively.

Any of the replaceable tips **14A** through **14E** on the extension **13** produces the necessary electrical connections to provide the appropriate readings. Moreover the 15° shifts of the aspect of the measurement plane relative to the probe axis **54** provide maximum flexibility in enabling contact with tissues in internal cavities that were not previously available. However, it will be apparent that these tips are easily manufactured and economical to produce and easy to use.

The probe **11** shown in FIG. **2** provides replaceable probe tips **14** that can attach and detach from an extension **13** that is fixed in the handle **12**. In some situations the examination process may contaminate the surface of the extension. Therefore it would be helpful if the extension were also replaceable. FIG. **8** depicts a modified probe **11A** that achieves this objective. As many of the components in the probe **11A** are similar to those in the probe **11** of FIGS. **2** through **4**, like numerals are used to designate like elements. Modified elements are designated by different references numerals annotated with "A".

Referring to FIG. **8**, the probe **11A** has a replaceable distal tip **14** attached to the distal end **31** of the modified extension **13A**. The modified extension **13A** connects at its proximal end to a modified handle **12A**. The interface between replaceable tips, such as the replaceable tip **14**, with different aspects and the distal end of the extension in probe **11A** is the same as shown with respect to the probe **11** in FIGS. **2** through **4**. Consequently, no further discussion of this connection is necessary.

The modification to the extension **13A** involves the termination at the proximal end. With this modification the proximal end of the extension **13A** contains a spring biased conductor assembly **80**, like the spring biased conductor assembly **50**. A conductor **81** in a passage **82** connects the spring biased conductor assemblies **50** and **80**. The modified extension **13A** also terminates at a distal end with an externally threaded portion **83**.

The handle **12A** includes a central conductive body **84** with a central passage **85** that receives a fixed conductor **86**. The distal end of the central conductive body **84** incorporates an internally threaded socket **87**. With this configuration rotating the extension **13A** relative to the handle **12A** provides attachment or detachment of the extension **13A** and the handle **12A**. The interaction of the spring biased conductor assembly **80** and the conductor **86** provides the necessary signal path to the connector **36** located in a proximal receptacle **90**. The modified extension **13A** therefore is an independent structure or

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subassembly that can be handled separately from both the replaceable probe tip **14** and the handle **12A**.

The handle **12A** additionally includes an insulating cover **91** overlying the central conductive body **84**. Machine screws **34** coated of a plastic material affix the insulating cover to the central conductive body **84**. A conductor **92** provides a signal connection to the conductor **86**. A ground connector **93** extends from the connector **36** to a ground connection **94** formed with the central conductive body **84**. Thus the conductive path established between the body of the distal tip **14**, the body of the modified extension **13A** and the central conductive body **84** is coupled back through the connector **36** to complete the sensing circuit.

As will now be apparent, this construction does provide the advantage of allowing modified extensions **13A** to be removed and replaced easily at a diagnostic facility. Consequently it is more readily adapted for use in a medical facility. It may also be possible to apply the concept by implementing modified extensions **13A** and handles **12A** where the extensions **13A** have different lengths. However, such a modification will require calibration of the dermal phase meter of FIG. **1** because changes in the length of the modified extension **13A** can alter the electrical characteristics of the probe **11A**.

FIGS. **9A** through **11B** depict three alternative embodiments of a probe tip construction that minimizes the potential for irritating sensitive tissue in a body cavity during a diagnosis. This particular probe is optimized for diagnosing ear problems by inserting the probe into the otic canal.

Each probe tip has certain common characteristics and distinguishing characteristics. Consequently FIGS. **9A** and **9B** describe one probe tip **100** in detail while the embodiment of FIGS. **10A** and **10B** and the embodiment in FIGS. **11A** and **11B** are described by highlighting the distinguishing characteristics. In the following discussion elements that are common to the structure shown in FIGS. **3** and **4** are used with suffix "A" in FIGS. **9A** and **9B**, "B" in FIGS. **10A** and **10B** and "C" in FIGS. **11A** and **11B**. Elements that are common to FIGS. **9A** through **11B** have corresponding suffices.

Referring now to FIGS. **9A** and **9B**, the probe tip **100** includes a central conductor **65A** comprising a head **101** and a center conductor **102** that extends along a measurement axis **75A** and terminates in line with a probe axis **54A**. The head **101** terminates in a surface **103** that is coplanar with a measurement plane orthogonal to the measurement axis **75A**.

An insulator **64A** includes a cylindrical portion **104** having an outer surface **105** lying in the measurement plane. At the opposite end the insulator **64A** terminates with an inwardly extending radial lip **106** that captures the head **101** and allows the passage of the center conductor **102**.

The outer conductor **60A** includes two pieces for facilitating manufacture. A first piece **107** includes a cylindrical wall **110** that terminates in a surface **111** at the measurement plane. At the other end an inwardly extending radial lip **112** captures the insulator **64A** and provides a passage for the center conductor **102**. The second piece **113** has a cylindrical wall **114** with internal threads **115** for being attached to threads, such as the threads on the threaded head portion **44** in FIGS. **3** and **4**.

The opposite end of the second piece **113** is machined to define an oblique surface parallel to the measurement plane. Specifically, an oblique extension **116** from the cylindrical wall **114** terminates at an end surface **117** that carries the first piece **107**. Similarly, a portion **120** of the wall **114** terminates at the end surface **117**. The angle along which the end surface **117** extends determines the angular aspect between the mea-

surement plane orthogonal to the axis **75A** and the probe axis **54A**. In this particular embodiment the aspect ratio is selected to be 45° .

In accordance with this invention, this structure is completed by overmolding a layer **121** that transitions to the measurement plane at a radius **122**. The layer **121** can be molded of any of a number of patient-compatible, compressible elastomeric materials. Materials taken from a class of various elastomers such as silicone, polyurethane and polyvinyl with a hardness of less than 90 Shore A, will provide the benefits of this invention. A probe tip formed with an overmold of urethane with a hardness of about 35 Shore A has provided particularly good results.

As will be apparent from FIGS. **9A** and **9B**, as the probe tip **100** is inserted into a body cavity, such as an ear, the overmolded, soft, compressible material layer **121** will ease into the tissue. This process then minimizes tissue irritation. The overmolded layer **121** also isolates the outer conductor **60A** electrically, as will be apparent to those skilled in the art.

FIGS. **10A** and **10B** depict a probe tip **130** that has the same basic construction as the probe tip **100** shown in FIGS. **9A** and **9B**. The difference is that the probe tip **130** establishes an angular aspect of 30° . In this particular embodiment, the outer conductor **60B**, insulator **64B** and center conductor **65B** have the same construction as the corresponding elements shown in FIGS. **9A** and **9B**. Element **113B** is modified so that the extension **117B** has a greater length parallel to the axis **75B** thereby to define a surface **117B** that is orthogonal to the axis **75B**. This also requires a machining modification of the portion **114B** such that the surface **117B** lies in an oblique plane relative to the probe axis **54B**. The overmolded layer **121B** has the same basic configuration as the overmolded layer **121** in FIGS. **9A** and **9B** modified only for purposes of accommodating the different configuration.

FIGS. **11A** and **11B** depict a probe tip **131** that again has a similar construction to the probe tip **100** in FIGS. **9A** and **9B** and has the same angular aspect. However the probe tip **131** has a smaller diameter. As before, except for dimensions, the outer conductor **60C**, insulator **64C** and center conductor **65C** have the same basic construction as the corresponding elements shown in FIGS. **9A** and **9B**. In this embodiment the overmolded layer **121C** has a conical surface **132** that extends back from a radius **122C**. Tapering in this matter provides still further immunity from tissue irritation.

This invention has been disclosed in terms of certain embodiments. It will be apparent that many modifications can be made to the disclosed apparatus without departing from the invention. For example, different electro mechanical connections using alternate conductive members and mechanical connections, such as a signal connection could be substituted. Differently shaped tips, extensions and handles could be substituted. The overmolded portions in FIGS. **9A** through **11B** can also be modified by substituting different materials and

that are patient compatible and compressible and by altering the specific shape in those figures. Therefore, it is the intent of the append claims to cover all such variations and modifications of the specifically disclosed embodiments as are covered by the claims.

What is claimed is:

1. In a dermal phase meter system including a data processing system and a probe, for providing input to the data processing system, said probe comprising:

A) a set of probe tips, each probe tip including:

- i) an outer electrode with first connection means for attaching said probe tip to said probe along a probe tip connection axis,
- ii) a center electrode lying along a measurement axis perpendicular to a measurement surface defined by the outer and center electrodes, and
- iii) an insulating medium spacing said outer and center electrodes whereby the angle between said probe tip connection axis and said measurement axis for a given probe tip establishes an angular aspect between the probe axis and the measurement surface and different probe tips in said set establish different angular relationships, and

B) probe tip support means for carrying a selected probe tip including a housing extending along the probe axis having:

- i) a first connection means at a proximal end thereof for connection to the data processing system,
- ii) a second connection means extending along the probe axis for engaging said probe outer electrode extending along the probe tip connection axis,
- iii) a third connection means in said housing proximate said second connection means and extending along the probe axis, said third connection means including an axially linearly displaceable, spring-biased, rigid conductor connected to said first connection means, each probe center electrode engaging and displacing said rigid conductor proximally as said probe tip is connected to said probe tip support means whereby said probe can operate with interchangeable probe tips that establish different angular aspects between said probe and measurement axes, and

C) a patient compatible, compressible elastomeric layer about said outer electrode of at least one probe tip.

2. A probe as recited in claim 1 wherein said elastomeric layer comprises an elastomer exhibiting a hardness parameter in a range of less than 90 Shore A.

3. A probe as recited in claim 1 wherein said elastomeric layer is formed of a material taken from a class which includes silicone, polyurethane and polyvinyl.

4. A probe as recited in claim 1 wherein said elastomeric layer is formed of urethane.

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